

Issue Snapshot— Substantial Equivalence



CENTER FOR
TOBACCO
PRODUCTS



The FDA Center for Tobacco Products was established in 2009 by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). This law ushered in a new era of tobacco control—giving FDA a powerful tool to regulate the manufacture, distribution, and marketing of tobacco products to protect public health.

Under the Tobacco Control Act, FDA must review certain tobacco products introduced or changed after February 15, 2007. To legally sell a new tobacco product in the United States that falls under FDA's regulation, FDA must issue a written order permitting the marketing under one of three pathways: a Premarket Tobacco Product Application, Substantial Equivalence Report, or Exemption from Substantial Equivalence Request.

Definition of a Substantially Equivalent Tobacco Product

To determine substantial equivalence, a new tobacco product is compared to a predicate tobacco product, which is a product that was commercially marketed in the United States as of February 15, 2007, or a product previously found to be substantially equivalent.

A new tobacco product is substantially equivalent to a predicate if FDA determines that it: 1) has the same characteristics as the predicate tobacco product and is in compliance with the Tobacco Control Act, or 2) has different characteristics but does not raise different questions of public health and is in compliance with the Tobacco Control Act. If the new product raises different questions of public health, the product is not substantially equivalent.

Substantial Equivalence Report

For FDA to determine whether a new tobacco product is substantially equivalent to a predicate product, a company must submit an application to FDA known as a Substantial Equivalence Report. If an incomplete report is submitted, FDA may issue a Refuse to Accept Letter. If a complete Substantial Equivalence Report is submitted, FDA performs a substantive review to determine if the new tobacco product is substantially equivalent to the predicate product selected by the company. FDA also reviews the application to make sure that the new product complies with all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

If the product is substantially equivalent and complies with the FD&C Act, FDA will issue a written marketing order permitting the product to be legally sold in the United States. A company cannot legally sell a new tobacco product if it receives an order from FDA stating that the product is not substantially equivalent.

FDA Decisions

During the substantial equivalence review process, FDA provides extensive feedback to the company on what information FDA needs to make a determination of whether the product is substantially equivalent. FDA has also developed guidance and resources to help companies provide complete submissions.

In June 2013, FDA issued the first decisions on Substantial Equivalence Reports. This marked the first time any tobacco product maker was told whether it was allowed to sell a product based on its potential public health impact. In February 2014, FDA issued its first decisions regarding marketed tobacco products. A finding of “not substantially equivalent” for four tobacco products meant that they could no longer be marketed, distributed, or sold in interstate commerce in the United States. FDA continues to regularly issue product review decisions.

For more information on substantial equivalence actions, please visit www.FDA.gov/tobaccomarketingorders.

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